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August 11, 2004

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Re: U.S. Patent Application No. 10/717,109 filed 11/19/2003
Applicant: Ram I. Mahato, et al
Title: **NOVEL CATIONIC LIPOPOLYMER AS A BIOCOMPATIBLE GENE
DELIVERY AGENT**
Group Art Unit: 1645
Attorney Docket No. T8948.CIP.2

Sir/Madam:

Transmitted herewith for filing and pursuant to 37 C.F.R. §§ 1.56 and 1.97 is an Information Disclosure Statement. Enclosed also are the following designated documents, as required under 37 C.F.R. §§ 1.97 and 1.98:

- ☒ Form PTO-1449 list of 24 references for your consideration.
- ☒ Legible copies of the listed references or their relevant portions not previously submitted.
- ☒ Legible copies of the listed non-patent documents and foreign documents or their relevant portions not previously submitted.
- ☐ Copies of U.S. patents and/or publications are not included pursuant to the Official Gazette Notice, dated Aug. 5, 2003, waiving the requirement of 37 C.F.R. 1.98(a)(2)(i).

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- ☐ All English translations of each non-English reference, if any, within the possession, custody, control or availability of anyone designated in 37 C.F.R. § 1.56(c) (see 37 C.F.R. § 1.98(c)).

The following are included within the Information Disclosure Statement if applicable and as required under 37 C.F.R. § 1.98:

- ☐ Concise explanation of relevance of each reference not in English and unaccompanied by an English translation.
- ☐ Statement that certain listed references not enclosed are substantially cumulative of an enclosed reference.
- ☒ Statement that certain listed references not enclosed were previously cited by or submitted to the Office in prior application nos. 10/083,861, filed on 02/25/2002 and 09/662,511, filed on 09/14/2000 (Patent No. 6,696,038), which are relied upon for an earlier filing date under 35 U.S.C. § 120.

In order to secure consideration of the items designated above, one or more of the following, if required, is also enclosed:

- ☐ Statement under 37 C.F.R. § 1.97(e)(1) or (2).
- ☐ Check No. _____, which includes the amount of \$0.00 (amount in § 1.17(p)) constituting the submission fee set forth in 37 C.F.R. § 1.17(p).

In the event that 37 C.F.R. § 1.97(c) applies and the Examiner is not satisfied that the Statement meets the requirements of 37 C.F.R. § 1.97(e), or in any other event remediable by a fee, please credit any over payment or charge any additional fees to Deposit Account No. 20-0100 of the undersigned.

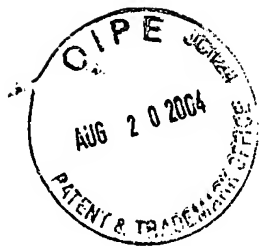
Respectfully submitted,



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PATENT APPLICATION
ATTORNEY DOCKET NO. T8948.CIP.2

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IN THE UNITED STATES PATENT & TRADEMARKS OFFICE

ART UNIT: 1645
EXAMINER:
APPLICANT: Ram I. Mahato, et al
SERIAL NO.: 10/717,109
FILED: 11/19/2003
CONFRM. NO.: 7310
FOR: A NOVEL CATIONIC LIPOPOLYMER
AS A BIOCOMPATIBLE GENE
DELIVERY AGENT

CERTIFICATE OF MAILING
UNDER 37 C.F.R. § 1.8

DATE OF DEPOSIT: *Aug 17, 2004*

I hereby certify that this paper or fee (along with any paper or fee referred to as being attached or enclosed) is being deposited with the United States Postal Service as first class mail with sufficient postage on the date indicated above and is addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Lucy Leek
Lucy Leek, Secretary

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir/Madam:

Please find, pursuant to 37 C.F.R. § 1.98(a)(1), the enclosed Form PTO-1449 which contains a list of all patents, publications, or other items that have come to the attention of one or more of the individuals designated in 37 C.F.R. § 1.56(c). Applicant respectfully submits that this Information Disclosure Statement is filed pursuant to:

- ☒ 37 C.F.R. § 1.97 (b)(1) or (3), within three months of the filing date of the application, or before a first office action on the merits, whichever occurs last;
- ☐ 37 C.F.R. § 1.97 (c), after a first office action on the merits, but before a Final Office Action or a Notice of Allowance, whichever occurs first, and is accompanied by either 1) a statement in accordance with 37 C.F.R. § 1.97(e), or 2) the fee set forth in § 1.17(p); or
- ☐ 37 C.F.R. § 1.97 (d), after a Final Office Action or Notice of Allowance, whichever occurs first, but on or before payment of the issue fee, and is accompanied by both 1) a statement in accordance with 37 C.F.R. § 1.97(e), and 2) the fee set forth in § 1.17(p).
- While no representation is made that any of these references may be "prior art" within the meaning of that term in accordance with 35 U.S.C. §§ 102 or 103, the enclosed list of references is disclosed so as to comply with the duty of disclosure set forth in 37 C.F.R. § 1.56.

Moreover, while no representation is made that a specific search of office files or patent office records has been conducted or that no better art exists, the undersigned attorney of record believes that the references listed, together with any other references which may have been previously submitted or listed, are the closest to the claimed invention (taken in its entirety) of which the undersigned is presently aware, and no art which is closer to the claimed invention (taken in its entirety) has been knowingly withheld.

☒ A legible copy of each listed U.S. Patent or publication (or relevant portion thereof) which was not previously submitted to, or cited by, the Patent Office is enclosed pursuant to 37 C.F.R. §§ 1.97 and 1.98.

☒ A legible copy of each of the listed non-patent literature and foreign documents (or relevant portions thereof) which was not previously submitted to, or cited by, the Patent Office is enclosed.

☐ Copies of cited U.S. patents and/or publications are **NOT** enclosed pursuant to the Official Gazette Notice, dated Aug. 5, 2003, waiving the requirement of 37 C.F.R. § 1.98(a)(2)(i).

☒ Copies of certain listed references in the accompanying Form PTO-1449 are **NOT** enclosed because, under 37 C.F.R. § 1.98(d), they were previously cited by or submitted to the Office in application numbers 10/083,861, filed 02/25/2002 and 09/662,511, filed 09/14/2000 (Patent No. 6,696,038), which are relied upon for an earlier filing date under 35 U.S.C. § 120.

The Commissioner is hereby authorized to charge any additional fees associated with this communication or to credit any overpayment to Deposit Account No. 20-0100.

Dated this 17th day of August, 2004.

Respectfully submitted,



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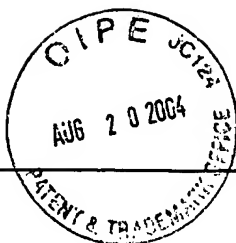
Enclosure

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LIST OF PRIOR ART CITED BY APPLICANT

GROUP
1645

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PTO-1449	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. T8948.CIP.2	SERIAL NO. 10/717,109
		APPLICANT MAHATO, et al	
		FILING DATE 11/19/2003	GROUP 1645
LIST OF PRIOR ART CITED BY APPLICANT			

OTHER PRIOR ART (Including Author, Title, Pertinent Pages, Etc.)

	AK	Felgner P.L., et al, LIPOFECTION: A HIGHLY EFFICIENT, LIPID-MEDIATED DNA TRANSFECTION PROCEDURE, Proc Natl Acad Sci USA 84: 7413-7417 (1987)
	AL	Gao, X. and Huang L., A NOVEL CATIONIC LIPOSOME REAGENT FOR EFFICIENT TRANSFECTION OF MAMMALIAN CELLS, Biochem. Biophys. Res. Commun. 179:280-285 (1991)
	AM	Nabel, et al., GENE TRANSFER IN VIVO WITH DNA-LIPOSOME COMPLEXES, Human Gene Therapy 3:649-656 (1992b)
	AN	Mosmann, T., RAPID COLORIMETRIC ASSAY FOR CELLULAR GROWTH AND SURVIVAL: APPLICATION TO PROLIFERATION AND CYTOTOXICITY ASSAYS, 65 J. Immunol. Methods 55-63 (1983)
	AO	Hans, S., et al, WATER-SOLUBLE LIPOPOLYMER FOR GENE DELIVERY. Bioconjugate Chemistry. 2001, Vol. 12, pages 337-345, see entire document.
	AP	Wang, D., et al, NOVEL BRANCHED POLY(ETHYLENIMINE)-CHOLESTEROL WATER-SOLUBLE LIPOPOLYMERS FOR GENE DELIVERY. Biomacromolecules. 2002, Vol. 3, pages 1197-1207, see entire document.
	AQ	Furgeson, D.Y., et al, MODIFIED LINEAR POLYETHYLENIMINE-CHOLESTEROL CONJUGATES FOR DNA COMPLEXATION. Bioconjugate Chemistry. 2003, Vol. 14, pages 840-847, see entire document.
	AR	Anderson, W. French, HUMAN GENE THERAPY, Nature, Vol. 392, 30 April 1998, pp. 25-30
	AS	Verma, Inder M., et al, GENE THERAPY – PROMISES, PROBLEMS AND PROSPECTS, Nature, Vol. 389. 18 September 1997, pp. 239-242
	AT	Miller, Nicholas, et al, TARGETED VECTORS FOR GENE THERAPY, Reviews, pp. 190-199
	AU	Crystal, Ronald G., TRANSFER OF GENES TO HUMANS: EARLY LESSONS AND OBSTACLES TO SUCCESS, Science 1995. Vol. 270 pp 404-410
	AV	Deonarain, Mahendra P., LIGAND-TARGETED RECEPTOR-MEDIATED VECTORS FOR GENE DELIVERY, pp. 53-69
	AW	Ogris, M., et al, PEGYLATED DNA/TRANSFERRIN-PEI COMPLEXES: REDUCED INTERACTION WITH BLOOD COMPONENTS, EXTENDED CIRCULATION IN BLOOD AND POTENTIAL FOR SYSTEMIC GENE DELIVERY, Gene Therapy 1996 6, pp. 595-605
	AX	Godbey, W.T., et al, POLY(ETHYLENIMINE) AND ITS ROLE IN GENE DELIVERY, Journal of Controlled Release 60 (1999) pp 149-160
EXAMINER		DATE CONSIDERED

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication with applicant.